

claims. Accordingly, upon entry of the additional claims herein, Claims 11 – 15, 17 – 20, and 23 – 31 will be pending.

Although not presented as a rejection or objection, the Examiner has asserted, without any supportive evidence, that the elected sodium hexametaphosphate will yield polyphosphate ion in water. As has been established in the present specification, and has been declared in the specification by Applicant (the inventor), the present dental erosion benefit is a result of the polyphosphate specified in the claims rather than any orthophosphate. In support of this establishment, Claim 11 has previously been amended to recite compositions comprising less than about 0.025% of orthophosphate, by weight of the composition. The Examiner has not presented any references which would indicate any motivation to substitute polyphosphate in place of the orthophosphate specified in the amended claims.

Prior to turning to the outstanding rejections in this application, Applicant wishes to clarify certain assertions of the Examiner with respect to the Office Action dated November 27, 2001. The Examiner, on the paragraph bridging pages 11 and 12 of the Office Action and those following this paragraph, has summarized several art references including Lussi *et al.*, Ruessner *et al.*, Muhler, and other various references. The Examiner has underscored that Applicant has “admitted” a prior art status of these references. It is now clarified for the record that Applicant has made no admission of the legal status of these references as “prior art” and that mere citation of such references in an Information Disclosure Statement is not tantamount to any such admission. Accordingly, Applicant respectfully requests that the Examiner refrain from making statements which are not supported by the record.

Applicant now turns again to the outstanding rejections in this Application:

The Rejections Under 35 U.S.C. §§ 102(b) and 103(a)

The Examiner has rejected Claims 11 – 15, 17 – 20, and 22 under 35 U.S.C. § 102(b) as being anticipated by mere recitation of a condensed phosphate or polyphosphate salt in low pH beverages in any of the various patents cited by the Examiner on Form PTO-892.

Applicant asserts that any rejection of Claims 11 – 15, 17 – 20, and 22 under 35 U.S.C. §§ 102(b) based on inherency and in view of any of the U.S. Patents cited on Examiner's Form PTO-892, is untenable and should be withdrawn. These kit claims are not anticipated based on inherency because each and every element of the claims is not disclosed, either expressly or inherently, in any of the cited patents. *See Verdegaaal Bros. v. Union Oil Co.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Indeed, a key limitation of kit Claims 11 – 15, 17 – 20, and 22 is “*information* that use of the [recited] beverage composition provides treatment against dental erosion.” This limitation

(the *information* in association with the recited composition) is not taught, suggested, or even inherently present in any of the cited patents. Moreover, there is no extrinsic evidence which may be used to show that the missing descriptive matter is necessarily, or even possibly, present in the cited patents. See *Continental Can Co. v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Accordingly, *Atlas Powder*, as cited by the Examiner, is irrelevant in view of the presently pending claims, as there is *no inherent presence of the claimed subject matter* set forth in the cited references. Any rejection of Claims 11 – 15, 17 – 20, and 22 based on inherency is therefore misplaced and should be withdrawn. If the Examiner persists with an inherency rejection in view of these kit claims, Applicant respectfully requests that the Examiner make clear the specific disclosure which renders the claims inherent and the specific rationale relating to applicability of *Atlas Powder*, specifically given that the expressly recited *information* cannot be an inherent feature of the previously described compositions.

Moreover, in the contemporary cases *In re Miller*, 164 USPQ 46 (CCPA 1969) and *In re Gulack*, 217 USPQ 401 (Fed. Cir. 1983), which were both subsequent to *Haller* (cited by the Examiner), articles comprising previously known compositions in association with information which was functionally related to such compositions, were held novel and non-obvious over the known compositions. For example, in *Miller*, which related to printed information on a measuring device, the Court stated:

[The Examiner's] characterization of printed matter as "unpatentable" is beside the point; no attempt is here being made to patent printed matter as such. The fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination. Here there is a new and unobvious functional relationship between a measuring receptacle, volumetric indicia thereon . . . and a legend indicating the ratio, and in our judgment the appealed claims properly define this relationship.

See *Miller*, at third paragraph from conclusion of opinion (emphasis added).

Indeed, the PTO expressly supports *Miller*, and *only* directs claim rejections in view of *Miller* when a mere arrangement of printed matter is claimed. See MPEP 706.03(a).

The Federal Circuit affirmed *Miller* in *Gulack*, even while recognizing that the "sole difference" between the claimed article and the prior art composition was the printed material. In *Gulack*, the Federal Circuit stated:

A functional relationship of the precise type found by the CCPA in *Miller* – to size or to type of substrate, or conveying information about [the] substrate – is not required. What is required is the existence of differences between the appealed claims and the prior art sufficient to establish patentability.

See Gulack, Section II, B.

Taken in the context of the present invention, Claims 11 – 15, 17 – 20, and 22 are indeed patentable over the cited U.S. patents. The information referenced in independent Claim 11, i.e., information that use of the beverage composition provides treatment against dental erosion, is clearly functionally related to the beverage composition itself. It is representative of the present discovery that the polyphosphate compounds recited in the claims are surprisingly effective against dental erosion. Moreover, the kits of Claims 11 – 15, 17 – 20, and 22 are directive, such that a consumer will understand the present discovery and have the ability to capitalize on such discovery. Thus, the utility of the present compositions is furthered because the consumer will understand the benefits, and be encouraged to utilize, the beverage composition based on this surprising and previously unknown use.

Applicant asserts that there are indeed differences between the cited art and the presently claimed kits, rendering the kits novel and unanticipated under 35 U.S.C. § 102. Like *Gulack* and *Miller*, the differences are largely related to the *information*. Moreover, this information is functionally related to the beverage of the recited kits (as highlighted in *Gulack*, yet “not required” under *Miller*). This information is a reflection of the present discovery that the recited compositions are surprisingly useful against dental erosion; Applicant has a legal right to protect this novel discovery. Applicant finds nothing in *Gulack* and *Miller* that should preclude Applicant from this legal right, and the Examiner has not provided guidance with regard to any rationale to the contrary. Applicant therefore strongly asserts that the Examiner should withdraw the rejection under 35 U.S.C. § 102(b) and allow the claims as pending.

Additionally, similar to the reasons stated above, Applicant further asserts that the kits of Claims 11 – 15, 17 – 20, and 22 would have been non-obvious over the cited references. In particular, the Examiner has combined any of the various patents cited by the Examiner on Form PTO-892 in view of each of Shibata *et al.*, “Antibacterial Action of Condensed Phosphates on the Bacterium *Streptococcus Mutans* and Experimental Caries in the Hamster,” *Archives of Oral Biology*, Vol. 27, pp. 809 – 816 (1982) (herein referred to as Shibata *et al.*) or McGaughey *et al.*, “Effects of Polyphosphates on the Solubility and Mineralization of HA: Relevance to a Rationale for Anticaries Activity,” *Journal of Dentistry Research*, Vol. 56, No. 6, pp. 579 – 587 (June 1977) (herein referred to as McGaughey *et al.*) and each of previously cited Muhler and McDonald *et al.*

To establish obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success in making the modification. Finally, the prior art reference must

teach or suggest all the claimed limitations and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure. *See In re Vaack*, 20 USPQ2d 1438 (Fed. Cir. 1991).

For the reasons stated above and as supported by established law, it would have been non-obvious to one of ordinary skill to use the recited polyphosphate compositions to treat dental erosion and to therefore provide kits which disseminate information regarding such treatment. Applicant asserts that, while the cited U.S. patents collectively disclose the polyphosphate compound utilized in the present claims, the patents fail to disclose, teach, or even suggest any use against dental erosion. Moreover, these references fail to suggest that the presently recited polyphosphate compounds would be useful as a substitute for the monosodium dihydrogen phosphate ("MDP", NaH_2PO_4) of Muhler and McDonald *et al.* for the purpose of treating dental erosion. Indeed, Claim 11 requires that the claimed beverage composition comprises less than about 0.025% of orthophosphate (*i.e.*, MDP), by weight of the composition. This is reflective of Applicant's unique and surprising discovery that the recited linear polyphosphates have effective utility against dental erosion, even in acidic environment.

Alternatively, the Examiner has rejected Claims 11 - 15, 17 - 20, and 22 as being unpatentable over the combination of Shibata *et al.*, McGaughey *et al.*, or Harris *et al.* in combination with Lussi *et al.*, Ruessner *et al.*, McDonald *et al.*, or Muhler. However, this combination of references fails to obviate the present invention as claimed. Rather, Lussi *et al.*, Ruessner *et al.*, McDonald *et al.*, and Muhler are actually supportive of the unexpected utility and benefit of the present invention. It is well-known in the art that acidic compositions are actually considered to exacerbate dental erosion (which occurs by direct action of acid on the enamel surface). *See* specification at page 1 and Lussi *et al.*, "Prediction of the Erosive Potential of Some Beverages", *Caries Research*, Vol. 29, pp. 349 - 354 (1995), which examined the erosive potential of many beverage compositions, all having a pH of less than 5. In contrast, the kits and methods of the present invention actually provide efficacy against dental erosion in this acidic environment. This would have been unexpected in view of the cited references and the literature at large, which fail to recognize the solution to the problems associated with acidic environment.

Moreover, Shibata *et al.* and McGaughey *et al.* (for example), which are also cited by the Examiner, recite the use of condensed phosphates *at elevated pH in the diet for the treatment of dental caries, not dental erosion*. As set forth in the present specification, dental erosion is distinguished from dental caries; dental caries is resultant of the direct action of bacteria on the enamel whereas erosion is rather related to the direct action of acid.

Taken together, therefore, the Examiner's cited combination of references fails to teach or even suggest the presently claimed kits. Firstly, and following the dictates of the law regarding

non-obviousness, there would have been no motivation or suggestion in the references to make any modification which would arrive at the present kits. The present kits claim beverage compositions having acidic pH and comprising the defined linear polyphosphates and explicitly less than about 0.025% orthophosphate, all together with information that these acidic beverage compositions provide treatment against dental erosion rather than caries. This is unexpected in light of the combined references, and in view of the literature *which attributes dental erosion to acidic environment*.

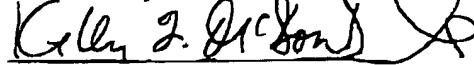
Secondly, but similarly, there would have been no reasonable expectation of success for the same foregoing reasons. It would not have been expected that an acidic composition would have utility against dental erosion, *since dental erosion is commonly attributed to the direct action of acid on the enamel* (rather than bacteria, which is causative of caries). Finally, *each combination of references cited by the Examiner fails to teach or suggest all of the claimed limitations*, particularly with regard to the definition of the linear polyphosphate compound, the acidity of the beverage composition, and the surprising information associated therewith. Respectfully, the Examiner has therefore failed to establish any obviousness of the presently claimed kits.

For all of the foregoing reasons, Applicant therefore asserts that the claimed kits are indeed novel and non-obvious over the cited references and in view of the consistent controlling authority. Applicant therefore respectfully requests the prompt allowance of the presently pending claims.

CONCLUSION

For all of the above reasons, and in view of the amendments and cancellations herein, it is respectfully requested that the Examiner withdraw the rejections under 35 U.S.C. §§ 102(b) and 103(a) and allow Claims 11 - 15, 17 - 20, and 23 - 31 as pending herein. If the Examiner believes that personal contact would be advantageous to the disposition of this case, he is respectfully requested to contact the undersigned at his earliest convenience.

Respectfully submitted,



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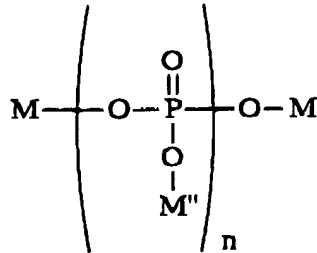
February 13, 2002

Attachment: Version With Markings to Show Changes Made

Version with Markings to Show Changes Made

Claim 23 has been added as follows:

23. A method of treating dental erosion comprising orally administering to a mammal a beverage composition having a pH of less than about 5; wherein the beverage composition comprises a compound having the structure:



wherein n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium, and wherein the beverage composition is substantially free of calcium and fluoride.

Claim 24 has been added as follows:

24. A method according to Claim 23 wherein the beverage composition has a pH from about 2 to about 4.5.

Claim 25 has been added as follows:

25. A method according to Claim 24 wherein the beverage composition further comprises a sweetener.

Claim 26 has been added as follows:

26. A method according to Claim 25 wherein M, M', and M'' are each sodium.

Claim 27 has been added as follows:

27. A method according to Claim 26 wherein n is an integer averaging from about 10 to about 30.

Claim 28 has been added as follows:

28. A method according to Claim 27 wherein the beverage composition has a pH of from about 2.7 to about 3.5.

Claim 29 has been added as follows:

29. A method according to Claim 28 wherein n is an integer averaging from about 13 to about 25.

Claim 30 has been added as follows:

30. A method according to Claim 29 wherein the beverage composition comprises from about 0.1% to about 20% of the sweetener, by weight of the composition.

Claim 31 has been added as follows:

31. A method according to Claim 30 wherein n is an integer averaging from about 19 to about 25.